K023525

MAR 2 6 2004

10. 510(k) Summary of the RETIscan/ RETIport

Company Name: ROLAND CONSULT
Friedrich-Franz-Str. 19
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Tel.: +49 3381 382621

Contact Person: Dipl. Ing. Matthias Mai

Legally Marketed Predicate Device

The RETI-Port/RETIscan-System is substiancially equivalent to Doran Maculoscope and the Espion System (K863956) manufactured by DORAN INSTRUMENTS, INC., and the VERIS System (K003442) manufactured by Electro-Diagnostic Imaging, Inc. These are Hardware and Software products. The RETI-Port-Scan device is substantially equvalent to the predicate devices with regard to device features and specifications, as well as intended use. All devices are visual evoked response test systems with similar operating requirements, that are based on standard clinical procedures.Devices consist of hardware and software to provide a photopic stimulus and an analysis of the evoked response data collected.

Device Description

Photopic stimuli are presented to the patient on an VGA-screen at a various number of elements in separately stimulated fields. Various modes are available for preferential stimulation of different retinal mechanism and isolation of signal from different retinal layers. Data are required by up to 8 recording channels using conventional EEG-electrodes. During the period of time that the system is aquiring data (1-20 minutes), there is a real time display of the raw and processed data presented to the user. Once the resulting individual waveforms are aquired, the signals are analyzed by software using algorithms for spatial filtering and artifact rejection. Data may be presented in a number of forms, including waves recorded at each of the points tested, color plots, or 3D topographical representation.

Intended Use

The RETI-Port-Scan system is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG) and visual evoked potential (VEP) signals, power spectral and topographic maps. These functions are controlled and interpreted by trained medical professionals.

Substantial Equivalence

Attribute	RETIscan RETIport	VERIS System	Doran Maculoscope and the Espion System (K863956)
Use:			
Intended Use: Generate photic signals and measure and display the electrical response signals generated by the retina and the visual nervous sytem	Yes	Yes	Yes
Intended Users: Ophtalmologists and trained medical technicians and professionals	Yes	Yes	Yes
Indications for Use: Electrophysiological Test Unit for quantifying the retinal response, measuring a parameter (VEP) related to retinal response	Yes	Yes	Yes
Intended Population: Patients with ophtalmic conditions	Yes	Yes	Yes
Intended use environment: Hospitals, clinics and physician offices	Yes	Yes	Yes
Physiological data collected: ERG waveforms	Yes	Yes	Yes
Compliance with Recognized standards: ISO/EN 60601-1-2 EN 55011: 03.1991	Yes Yes	Yes Yes	

Performance Data

The RETIscan/RETIport System has been tested for electrical safety and has received a certificate of compliance with EN60601-1 Standards.

Safety

The 21" monitor stimulator complies with IEC601-1-2

The Ganzfeld-stimulator and the Miniganzfeld-stimulator complies with IEC 60601-1

The patients eye is exposed to a normal visual light radiation. The level of exposure was measured and represents no risk to the patient.

Effectiveness

All Stimulators provide equivalent stimulation for the purpose of evoked potential (ERG, VEP) recording in all regards (stimulus luminance, chromaticity and size of the stimulated visual field).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2004

Mr. Matthias Mai
Roland Consult
Elektrophysiologische Diagnostik SY
Friedrich-Franz-Strasse 19
Brandenburg
Germany D 14770

Re: K023525
Trade/Device Name: RETIscan RETIport
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked response photic stimulator
Regulatory Class: II
Product Code: GWE
Dated: February 5, 2004
Received: February 9, 2004

Dear Mr. Mai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K023525

Device Name: RETIscan RETIport

Indications For Use: Electrophysiological Test Unit for quantifying the retinal response, measuring a parameter (VEP) related to retinal response

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K023525

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)